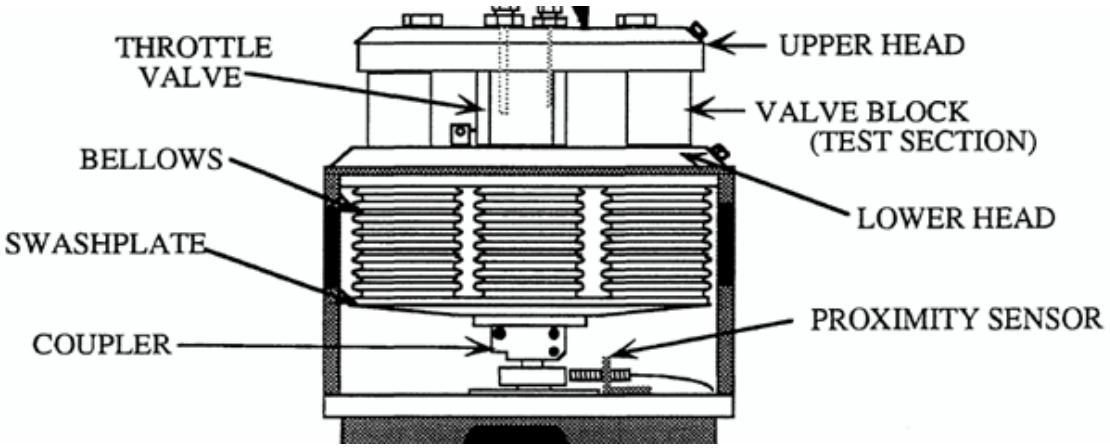
Exhibit H


THROTTLE VALVE
UPPER HEAD
VALVE BLOCK (TEST SECTION)
BELLOWS
LOWER HEAD
SWASHPLATE
PROXIMITY SENSOR
COUPLER

SICN
M6E
9320-01A
DC5000
9320-01C

OPERATING INSTRUCTIONS

M6

SIX-POSITION HEART VALVE DURABILITY TESTING DEVICE

Dynatek Dalta® Scientific Instruments
Fourth and Main
Post Office Box 254
Galena, MO 65656
(417) 357-6155

September 1993
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M6 MANUAL

Included with the basic M6 manual are these extra attachments:

1. Dayton motor instructions
2. Watlow 985 controller instructions and troubleshooting
3. ~~Stentless~~ test section assembly drawing (optional)
4. ~~XSC wiring~~ diagram (optional)
5. ~~Endevco~~ transducer information sheets (optional)
6. ~~Endevco~~ Transducer Manual (optional)
7. Bodine motor controller instructions
8. Monarch tachometer manual
9. IVO NE 212 manual
10. Proximity sensor instructions

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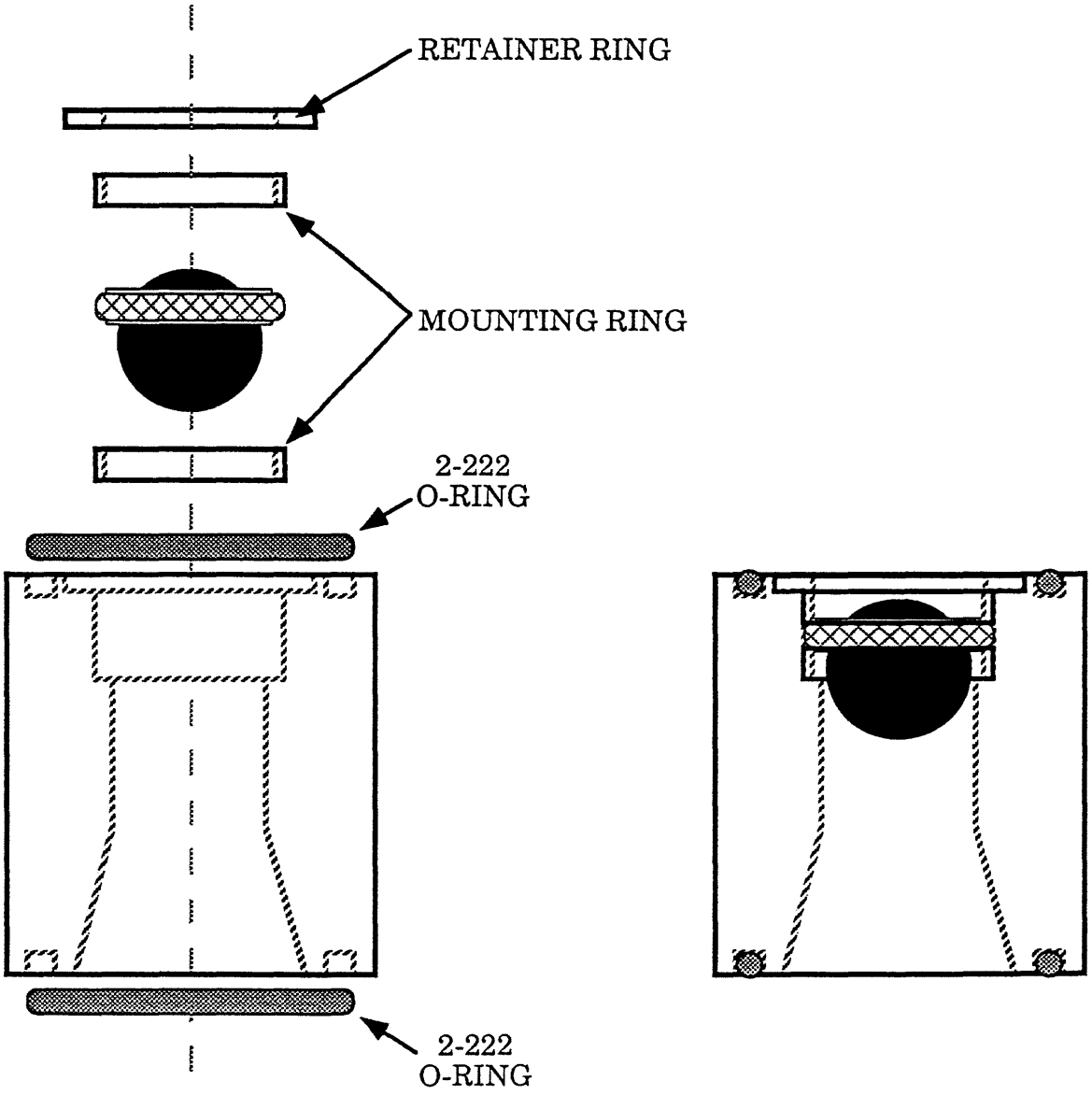
TEST SECTION ASSEMBLY



DYNATEK/DALTA
DYNATEK LABORATORIES, INC.
Fourth & Main
P.O. Box 254
Galena, MO 65656-0254
Tel. (417) 357-6155
Fax (417) 357-6327

GENERAL DESCRIPTION

The M6 is a six-position heart valve durability/fatigue testing machine which has been designed to provide years of continuous testing with little or no maintenance and with very little attention.

A swashplate drive is used to compress six bellows which supply each of the six valve compartments. A common inlet flow chamber is used to provide a common fluid passage for pressure and temperature stabilization. There is some vibration with this drive arrangement but it is much less than with a reciprocating oscillator.

There are four sections which make up its assembly: The motor drive with the proximity sensor; the pumping unit (swashplate, coupler, and bellows); the testing chamber (upper and lower heads, throttle valve, valve blocks and capacitance tank) and the controller (see Figure 1A).

THEORY OF OPERATION

As the motor shaft turns, the adjustable tilting coupler rotates and pulls the swashplate down, extending the bellows. This draws fluid down into the bellows through the now opened valve being tested. As the rotation continues, the swashplate is returned upward, compressing the bellows, causing the fluid to reverse direction and close the valve. Further bellows compression increases the pressure behind the valve, loading the leaflets or occluders. Fluid now escapes through the bypass port, through the throttle valve and into the central reservoir where it is then available to the upper head above the valves for another cycle. Closing pressure is a function of motor speed, swashplate deflection and throttle position.

UNPACKING INSTRUCTIONS

The M6 will be shipped in three separate packing cases. Each box is marked with its contents. Unpack each box carefully. When removing the M6 from its case, reach down into the case and grasp the machine by the upper notches, not by the plexiglass heads. The control box and accessory kit are in the other two cases.

The machine itself should be placed either on a low, sturdy table at a convenient height for valve observation or on the floor. When we do testing here at Dynatek Dalta Scientific Instruments, we prefer to set the machine on a mat on the floor. This will reduce the risk of the machine "walking" off a table due to vibration. The mat will protect the floor from minor damage. You may also use the top piece of packing foam from the M6 packing case. Also, the capacitance tank should be placed so that it is above the water level of the M6 (see Figure 1A); if the capacitance tank is on the same level as the M6 there is an increased risk of negative pressure. If the machine is placed on the floor, you can easily put the capacitance tank and controller above it on a table. The capacitance tank will be installed between the controller and the M6, so you may want to put both the controller and the capacitance tank on the same surface. Shim the table legs as necessary to prevent rocking. Be certain all components are level.

The tools, heater, sensor, stopcock, tubing connector, etc., are packed together as the accessory kit in the smallest box.

The DC motor cord is inside the motor case (the bottom part of the machine). To access, carefully tilt the machine sideways and unwrap cord from the bottom, pulling it out through one of the bottom notches.

SET UP

Following are step-by-step instructions for setting up the M6. These instructions contain little more than the pertinent information about the machine and its components needed to set it up and get it running. Further details will be given in the "DESCRIPTIONS" section later in the manual; you will be directed to the correct sections for this information. The following instructions are meant to be followed easily without the need to read the entire manual. If you have any questions, please call our main office.

Once you have unpacked the M6 and positioned it and the capacitance tank as you want them, you can begin setting up the machine. See Figure 1B. Plug the motor power cord into the DC OUTPUT plug in the back of the controller. Then remove the front panel of the upper (bellows housing) cylinder (15). The sectors with the cutout handles are the side panels. These are attached with four 1/4"-20 screws. At the top there are two 1/4"-20 x 3/4" buttonhead cap screws which can be removed with a 5/32" hex wrench. At the bottom are two 1/4"-20 x 1" cap screws that are removed with a 3/16" hex wrench. Removing the front panel will allow you to access the bellows, coupler and proximity sensor. The proximity sensor, which sends signals to both the speed indicator and the IVO counter, is mounted on the motor plate pointing toward the rotating shaft. Pull the proximity sensor wire (14) out through the cutout handle in the nearest side panel.

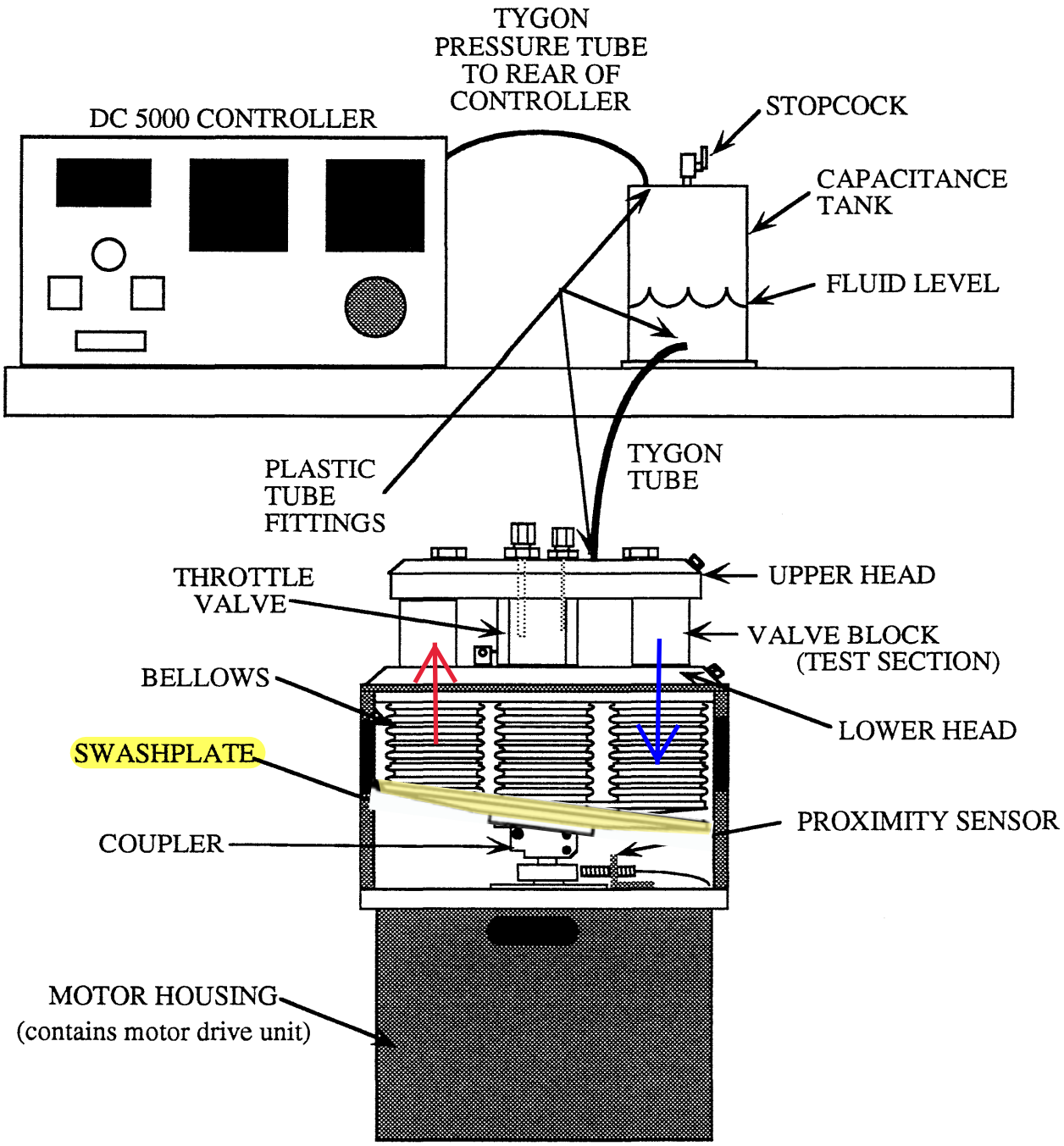

TYGON
PRESSURE TUBE
TO REAR OF
CONTROLLER
DC 5000 CONTROLLER
STOPCOCK
CAPACITANCE
TANK
FLUID LEVEL
PLASTIC
TUBE
FITTINGS
TYGON
TUBE
THROTTLE
VALVE
UPPER HEAD
VALVE BLOCK
(TEST SECTION)
BELLOWS
LOWER HEAD
SWASHPLATE
PROXIMITY SENSOR
COUPLER
MOTOR HOUSING
(contains motor drive unit)

FIGURE 1A

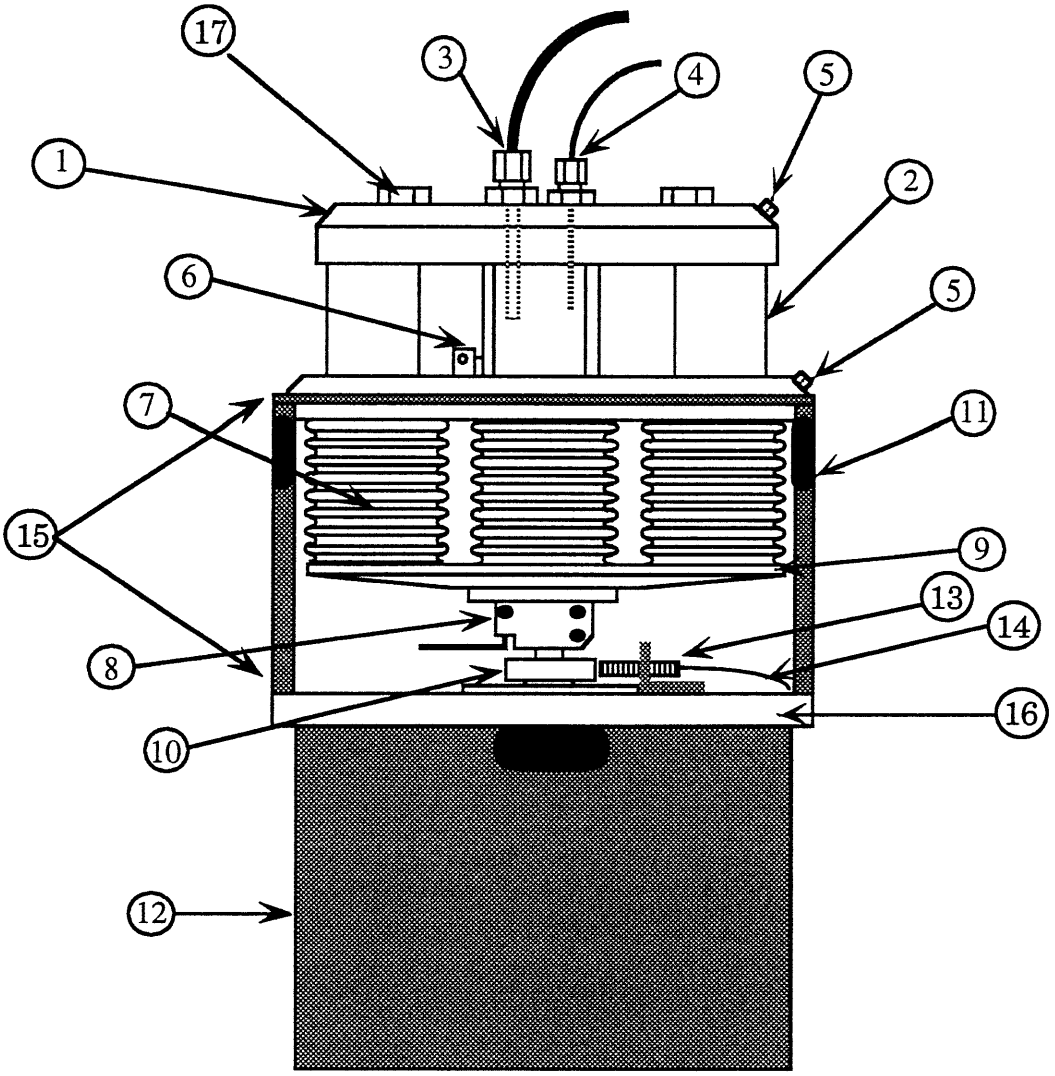


Figure 1B - Machine with Two Sectors Removed To Show Swashplate Tilt Coupling and Jack Screw Wrench

1 Upper Head
2 Test Section
3 Cartridge Heater
4 Temperature Sensor
5 Transducer Ports With Plugs
6 Throttle Valve And Jack Screws
7 Bellows
8 Tilt Coupling With Jack Screw Wrench Installed
9 Swashplate
10 Thrust Collar And Proximity Sensor Target
11 Top Cylinder Sectors (Shown With Two Removed)
12 Motor Housing Cylinder
13 Proximity Sensor
14 Proximity Sensor Wire
15 Bellows Housing Cylinder
16 Motor Mounting Plate
17 Nylon Bolts

Next you will hook up the controller. (For more information, see section "Control Module.") The control module (Figure 2) is designed to control speed, temperature, systemic pressure operating range, and cycle count for the M6. Plug the AC power cord (L) into the line stabilizer/conditioner LS600 (which is supplied with the M6) and plug the line stabilizer/conditioner into a 115 VAC 60Hz outlet. Plug the proximity sensor wire from the M6 to its input (N), and tighten the locking ring.

In our age of high tech testing it's interesting to note that bubble removal is one of the biggest challenges facing a valve tester. It must be stressed, however, that the presence of bubbles in the test fluid can erode both leaflet and occluder type valves. While setting up, be patient and the bubbles will dissipate. Also, note during this time if any vibration is causing the instrument to "walk." If it does, padding, restraints or leveling may be necessary.

We have found that the most tenacious bubbles are within the convolutions of the bellows. As a result, we recommend two separate set up procedures. The first is designed to initiate a dry machine or change the nature of the fluid in an already set up instrument. The second is to install the valves into an already initialized machine or change the valves in a completely set up instrument. To accomplish the latter, simply follow Steps 18-45.

To Set Up a Dry Machine (SET UP mode)

1) Install the throttle valve (for more information, see sections "Testing Chamber" and "Pumping Unit"). This is the cylinder which fits in the middle of the lower head, with holes at the bottom that match up with the ports in the lower head. Position the throttle valve so that the tab on the bottom sits between the two blocks on the top of the lower head. Secure the cap screws located here with the supplied ball driver. These cap screws are used to position the throttle valve and should be snug, not tight, against the tab of the throttle valve. The holes at the bottom of the throttle valve should be at the center of their adjustment range. DO NOT OVERTIGHTEN!

2) Install a set of empty valve blocks (for more information see section "Valve Installation"). Make sure the o-rings are placed correctly in the upper and lower grooves of the test section for a good seal. Push test sections flush against the stops on the lower head.

3) Connect sensor fitting, 1/4" heater fitting, 3/16" auxiliary heater fitting and nylon capacitance tank fitting to top of upper head (For more information, see section "Pumping Unit.")

4) Place upper head on test sections. Insert and tighten the 1/2" nylon bolts in a symmetrical sequence. If the bolts were numbered 1-6,

FIGURE 2 CALL OUT

DC5000 CONTROLLER

A- Digital speed indicator
B- Programmable counter
C- Temperature controller
D- Drive motor start
E- Drive motor speed adjust (10 turn)
F- Drive motor stop
G- Set up indicator lamp
G2- System pressure gauge
H- Pressure tube to low/high pressure cut off switch
I- Set up-Run to bypass pressure switch and counter presets
J- Main power fuse
K- Main power switch
L- 115 VAC, 50/60 Hz power in
M- Variable DC power out to drive motor
N- Proximity sensor connector
O- Heater socket
P- Temperature sensor socket
Q- Trigger out

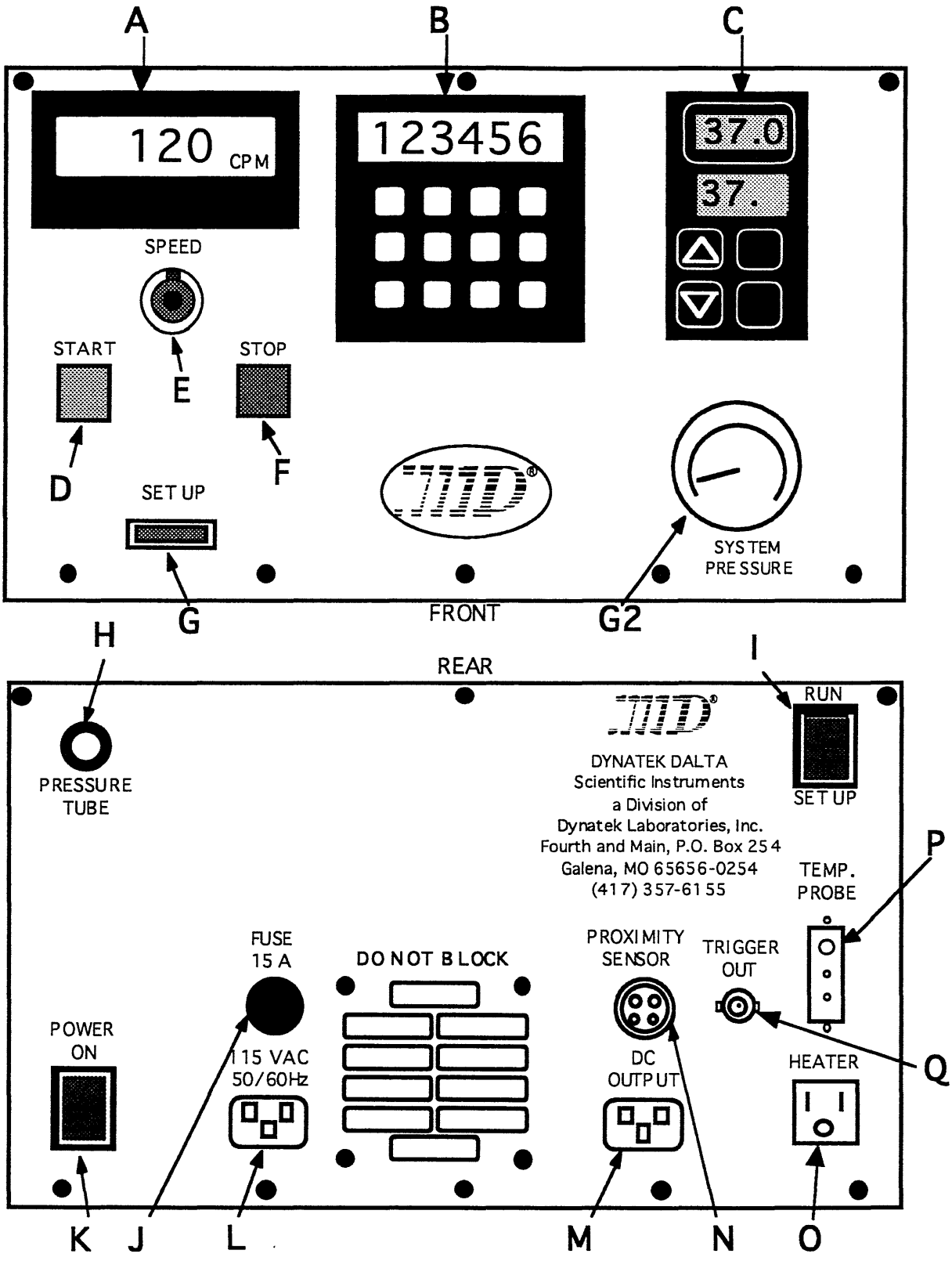


FIGURE 2

Rev. 9/15/93

tighten them 1,4,2,5,3 then 6. Continue following this pattern, gradually making the bolts tighter until the test sections are snug and all o-rings seated. While you are tightening, keep the test sections tight against their stops. (NOTE: Hand tighten only.)

5) Put plugged tube (supplied) onto the nylon capacitance tank fitting in the upper head.

6) Place a full tank of your testing fluid above the M6 and start a siphon with the five foot length of 1/8" Tygon tubing that is supplied. (For more information about testing fluid, see section "Setting the Pressure and Flow Rate.") Remove the top female cap of the heater fitting. Put the tubing into the heater port (largest hole) and feed it all the way to the bottom of the throttle valve.

7) Now you will fill the bellows. (For more information about bellows, see section "Pumping Unit.")

8) Let the machine fill slowly. Be sure to leave the sensor out so that air may escape through the sensor fitting hole.

9) When the fluid level reaches the sensor fitting, stop filling before the machine overflows. Air bubbles will be present.

10) Insert the sensor into the sensor fitting and tighten.

11) Remove the fill tube from the M6 and fit the funnel with the Tygon tube adapter over the threads of the heater port. Add enough fluid to fill the funnel tube to a depth of 2". For large bubbles, you may carefully tilt the machine sideways until the bubbles collect under the heater fitting and escape. Replenish fluid.

12) Before you begin debubbling the bellows, you must set the swashplate for the proper deflection. The greater the deflection of the swashplate, the greater the stroke volume of the six bellows. In general, a larger valve will require a larger displacement of volume. Using the 3/16" T-handle hex wrench, loosen the three cap screws on the side of the coupler, then turn the coupler so that the notch is facing the front of the machine. Take the cut-down 1/8" hex wrench and insert it into the jack screw; turning to the right will increase the deflection of the swashplate, turning to the left will decrease deflection. A deflection of approximately 2mm is appropriate for debubbling. Measure the deflection at the periphery of the swashplate using a ruler and turning the coupler one full revolution.

13) Tighten the single cap screw first, while putting downward pressure with your hand on the edge of the swashplate in line with the notch in the coupler. Tighten the other two cap screws.

14) On the back of the controlleryou will find a switch for SET UP and RUN. (For more information, see section "SET UP/RUN Switch.") Switch to SET UP. Turn the speed dial counterclockwise to zero. Turn on the controller. Press the START button and hold 2-3 seconds. **WARNING: BE CERTAIN THE HEATER IS NOT PLUGGED IN.** Adjustment of the speed is performed via a 10 turn locking dial (see Figure 2, letter E) on the front panel of the controller. Directly above is the digital speed readout; this meter reads in revolutions (or cycles) per minute, and is updated once every second. (For more information about speed control, see section "Speed Control.")

15) Slowly increase the speed to 700 or 800 rpm. You should not exceed this speed when debubbling the bellows.

16) Maintain 700-800 rpm for 5 seconds, then reduce the speed to zero rpm for 30 seconds. You will note that the released bubbles will have a tendency to vortex and exit through the funnel. Be sure to maintain the fluid level in the funnel during the procedure by adding more fluid as it is drained into the machine. DO NOT LEAVE MACHINE UNATTENDED WHEN IN SET UP MODE.

17) Repeat this speed cycling until most of the visible bubbles (larger than a period on this paper) are removed, perhaps 10 to 20 repeats.

18) Remove as much fluid as possible from the funnel with a syringe.

19) Remove the funnel from the heater fitting, insert the tube and start a siphon. Drain fluid to just below test sections.

20) Remove the test sections by loosening the 1/2" nylon bolts in the upper head and sliding the sections out.

21) Place the valves in the test sections with the appropriate o-rings. Two or three different sizes and/or types of valve may be installed simultaneously if appropriate blocks are used and similar pressures are obtainable. When two types or sizes of valves are to be run simultaneously, their positions should be alternated. If three different pairs of valves are to be run, each pair should be run in diametrically opposite positions. (For more information on valves, see sections "Testing Chamber" and "Setting the Pressure.")

22) Replace the test sections in the lower head. If the valves you are using have any protrusions above the top of the test sections (i.e. tilting disk mechanical valves) you must remove the upper head before replacing the test sections in the lower head. Make sure the o-rings are placed correctly in the upper and lower grooves of the test section for a good seal. Push the sections flush to the stops on the lower head.

23) Replace the upper head. Tighten down the 1/2" bolts. Hand tighten only! Lightly tighten opposite pairs using both hands for an even pull-down. After the initial tightening, loosen all six bolts about one turn, check the position of the blocks and retighten the bolts. This double tightening procedure assures correct alignment. See Step 4 for details.

24) Repeat Steps 5-11 to debubble the test sections, but increase the speed only to 500-600 rpm. Watch for bubbles under the valve leaflets. NOTE: Never bring the machine above 600 rpm when debubbling test sections with valves installed. BE PATIENT! DO NOT LEAVE THE MACHINE UNATTENDED WHEN IN SET UP MODE.

25) Install the heater into the heater fitting on top of the upper head.

26) Attach the upper and lower plastic tube fittings, o-rings and stopcock to the capacitance tank. (For more information, see section "Testing Chamber and Capacitance Tank.")

27) Connect the 1/8" tubing (fluid supply line) to the bottom fitting on the capacitance tank and clamp off the tube.

28) Remove the plugged tube from the capacitance tank fitting on the upper head.

29) Fill the capacitance tank to 1" past the bottom fitting. To do this, use the syringe provided and fill through the stopcock.

30) Bleed the fluid supply line. Unclamp the line until it is filled with fluid, then attach to the fitting on the upper head of the M6 and reclamp as close to the machine as possible.

32) Place the fluid supply line on the capacitance tank fitting on the upper head.

33) Replace the heater in the fitting and tighten down. NOTE: If bubbles accumulate after heater is installed, you may try to remove them through the stopcock or by CAREFULLY tilting the machine until the bubbles collect under one of the port screws. Unclamp the supply line from capacitance tank. Loosen the port screw just until the air escapes, then retighten. Reclamp the supply line. Be careful not to remove the port screw completely or fluid will leak out.

34) Affix the pressure tube from the controller to the upper fitting on the capacitance tank.

35) Check that the systemic pressure is zero and the tube from the capacitance tank is clamped as close to the machine as possible.

36) Install the calibrated pressure transducers. (For calibration information see section "Transducer Calibration.") Pressure transducer ports are provided in the top and bottom manifolds at each valve block position. These ports are 10-32 tapped for miniature transducers (e.g., Endevco 8510-5). If desired, a series of stopcocks can be used to facilitate easy transfer of the pressure transducers from one valve position to the next. Remove the port screw above the test section you are working with. Void this port of any air by quickly opening and closing the clamp on the pressure tube. (If the system is closed no fluid will leak out.) Remove the protective red cover on pressure transducer B; insert the transducer into the port and screw it down; do not let the transducer wire twist. Finger tightening should be sufficient for a good seal.

37) Follow the above procedure for the lower port of the same test section, inserting transducer A.

38) Plug the transducers into the XSC box.

39) Connect the XSC outputs to the oscilloscope. The B transducer must be connected to the inverting channel on the oscilloscope. The B transducer reading will be subtracted from the A transducer reading to give you the closing pressure.

40) Release the clamp on the fluid supply hose from the capacitance tank.

41) The systemic operating pressure is displayed on the front panel gauge (G2), and is monitored by a high/low pressure switch which is connected to the capacitance tank. Adjust the systemic pressure by pressurizing the capacitance tank to 2-3 psig as indicated on the pressure gauge. (For more information about systemic pressure, see section "Systemic Pressure Range.") Attach a syringe or rubber bulb to the stopcock on top of the capacitance tank. Open the stopcock, add air and close the stopcock to refill the syringe with air.

42) Start the drive, bring it up to speed and check the closing pressure. Adjust the throttle or swashplate deflection to attain the desired closing pressure. Example: The running speed desired is 1000 cycles per minute. Start with a 2mm swashplate deflection and the throttle valve halfway open. Bring the speed up slowly, observing the pressure trace on the oscilloscope. If your desired closing pressure (e.g., 120mmHg) is reached before attaining the speed you want, decrease the swashplate deflection and repeat the above procedure. If you reach the desired speed before attaining the correct closing pressure, increase the deflection. The throttle valve can be used to make minor adjustments and for fine tuning. (For more information on closing pressure, see section "Setting the Pressure and Flow Rate.")

43) Press the STOP button and return the speed dial to zero. Open the stopcock on the capacitance tank and bleed off systemic pressure, then clamp off the capacitance tank supply line close to the machine.

44) Remove the transducers from the M6 pressure ports one at a time.

45) Remove the clamp from the capacitance tank supply line. Repressurize the capacitance tank to the previous pressure. Close the stopcock. If you wish, you may now zero the counter. (See next step.) Plug the heater and the temperature sensor into the rear of the controller. Turn the speed control dial (E) to zero and depress the green start button (D). Slowly bring it up to the correct speed. If the drive will not engage, check the capacitance tank pressure. If the capacitance tank pressure proves to be correct, switch to SET UP and start. If the drive starts, it may be possible that the pressure switch needs to be adjusted. (See section "Pressure Switch Adjustment.") When the temperature reaches the setpoint, you may switch to the RUN mode. (See section "Temperature Adjustment" for more information.) The temperature controller is shipped preset for 37° C.

46) To zero the counter, press the following in order: PR - F - arrow (➜) - PR.

DESCRIPTIONS

The following section gives more specific information for each component of the M6.

Motor Drive and Proximity Sensor

A 1/4 h.p. DC motor is hung vertically from the motor plate. This plate is 1/2" steel for a mass-inertia base. A thrust bearing is installed in the plate and secured with a collar to provide positive positioning and to remove thrust load from the motor bearings.

The aluminum base cylinder is scalloped to provide air circulation to cool the motor.

The proximity sensor which sends signals to both the speed indicator and the IVO counter is mounted on the motor plate pointing toward the rotating shaft. If an adjustment is found to be necessary, the tip should be 0.008" from the welded strip located on the rotating shaft collar. (For more information, see section "Proximity Sensor.")

Pumping Unit

The pumping module consists of an adjustable tilt angle swashplate and coupling, bellows and the lower head.

A socket head set screw in the cut out step in the lower half of the tilt coupling is used to change the tilt angle of the swashplate (see Figure 1B). Loosen the three cap screws about 1/2 to 1 turn and turn the jack screw with the wrench provided to raise or lower the tilt angle. The tilt-drive amplitude is measured at the periphery of the swashplate. To measure the swashplate deflection, turn the coupling by hand and measure the min-max deflection for one revolution.

The bellows are secured to the swashplate with stainless steel disks and 1/4"-20 socket head cap screws which are accessible through the top of the bellows. Positive sealing is maintained by a silicone gasket under the disks and silicone sealant around the cap screws at the time of initial assembly. The bellows should not be removed except for replacement in case of failure. The bellows are secured to the top plate with clamping rings and sealed with silicone rubber o-rings. In case replacement is necessary, the clamping ring screws are accessible through holes in the swashplate. A 7/64" ball driver is supplied for these screws.

The lower head is ported from the valve discharge region into the center return reservoir. The inertial pressure drop across these ports, plus the resistance and inertial effect of flow through the center reservoir, supply the closing pressure to load the valves.

Pressure transducer ports are provided in the upper and lower heads at each valve block position. These ports are 10-32 tapped for miniature transducers (e.g., Endevco 8510-5, supplied upon request). If desired, a series of stopcocks can be used to facilitate the easy transfer of pressure transducers from one valve position to the next. (For more information about the pumping unit, see section "Pumping Unit" under "Service and Maintenance.")

Testing Chamber and Capacitance Tank

Individual valve blocks allow the insertion and removal of any one valve at a time. Two or three different sizes and/or types of valve may be installed simultaneously if the appropriate blocks are used and similar pressures are obtainable.

When two types or sizes of valves are to be run simultaneously, their positions should be alternated. If three different pairs of valves are to be run, each pair should be run in diametrically opposite positions.

The square shape of the block allows for minimal optical distortion from three sides. The valves are installed in a shoulder recess in the top of the blocks. O-rings may be used to facilitate installation by providing a good fit, and to adapt similar types and/or sizes of valves to a given set of blocks. Valve blocks may be ordered for specific valve sizes.

The blocks are sealed between the top and bottom plates with o-rings.

The upper head contains the inlet flow passages and the heater and temperature sensor ports. The cartridge heater and fitting is installed in the center tapped hole and the sensor and fitting is installed in the adjacent tapped hole.

The pressure transducer ports (and plug screws) are near the end of the flow passages in the upper head with a matching set in the lower head (see Figure 1B, number 5).

A throttle valve is used to adjust the closing back pressure on the valve. It may be adjusted without emptying the system by turning the cap screw at the base of the throttle valve with the supplied ball driver. If any binding or resistance is encountered, the following procedure should be implemented: With the capacitance tank depressurized, loosen the 1/2" nylon bolts in pairs going around the top of the upper head sequentially, loosening them about one-half turn, then retighten to finger tight. This relieves the pressure on the throttle valve just enough to be able to move it, but not enough to cause leakage. After all of the bolts

have been loosened, the throttle may be adjusted by turning the cap screw at the base of the throttle with the supplied ball driver. Retighten the bolts, pressurize the capacitance tank (see below) and check the closing pressures. There are three different throttle valves available. A 3/4" bypass hole is supplied for tissue valves, a 17/32" bypass hole is supplied for mechanical valves and a 5/16" bypass hole is supplied for biomaterial test sections.

An acrylic capacitance tank is used to buffer small variations in the systemic pressure which arise from transient small leakage and thermal effects. It is installed between the controller box and the testing unit via Tygon tubing. Whenever the system pressure is adjusted or released it should be done through the stopcock on the capacitance tank. (For more information about the throttle valve and capacitance tank, see section "Setting the Pressure.")

Valve Installation

Valves are installed in each of the separate valve blocks using suitable silicone o-rings where necessary depending on the valve type and geometry. Valve test section blocks are tailored to the specific valve type and size. It may be possible to run two sizes of valves in the same size valve block. Adapters (often just o-rings) may be necessary.

If you have any questions, please contact Dynatek Dalta Scientific Instruments and we will evaluate your valve dimensions and recommend test sections or mounting procedures.

Loosen the six 1/2" nylon bolts 2 or 3 turns and lift the top plate to free the valve blocks so that they will clear the transducer port screws.

Install valves with valve discharge downward. Valves that are 25mm nominal size and smaller require inlet adapters (furnished with test sections on request). Small valves may also be adapted easily using thicker (3/16 or 1/4") cross-section o-rings.

Replace the valve blocks with their orange silicone o-rings. Note that the valve block bases may be slightly rectangular. The smaller dimension is fitted back into the block positioner brackets on the bottom plate and centered. Push opposite pairs of blocks into position. Tighten down 1/2" bolts. Hand tighten only! These plastic bolts are furnished to facilitate hand tightening and prevent the use of a wrench. Lightly tighten opposite pairs of bolts using both hands for an even pull-down. After the initial tightening, loosen all six bolts about one turn, check the position of the blocks again, as above, and retighten the bolts. This double tightening procedure assures correct alignment.

The machine is delivered with a pump-bellows drive amplitude of about 1mm.

Valve Removal

One or more valves may be removed for inspection or replacement. It is only necessary to drain the top module. Bleed the fluid pressure off the system by opening the stopcock.

Unscrew the heater fitting nut and remove the heater with the nut. Insert a tube into the bottom of the center chamber and siphon off the fluid at the bottom of this chamber. This volume will be less than one liter.

Loosen the hold-down bolts enough to free the valve block to be removed and pull the block out. Be careful not to drop or pinch the o-rings. The top plate may be removed if desired. If the valves you are using have any protrusions above the top of the test sections (i.e., tilting disk mechanical valves) it will be necessary to remove the upper head.

Control Module

The control module (see Figure 2) is designed to control the speed, temperature, systemic pressure operating range, and cycle count for the M6. (For more information about the control module, see section "Inside the Control Console.")

Speed Control

The speed of the M6 is regulated by a closed loop feedback system which can maintain relatively constant speed while line voltage and motor temperature vary.

Adjustment of speed is performed via a 10 turn locking dial (E on Figure 2) on the front panel of the M6 controller. Directly above this dial is the digital speed readout (A on Figure 2); this meter reads in revolutions (or cycles) per minute, and is updated once every second. The range of the speed control is approximately 100-2000 rpm depending on load, line voltage, and motor temperature.

Temperature Adjustment

The temperature of the M6 is maintained by a Watlow Model 985A time proportioning controller with matched RTD temperature sensor, and a 100 watt cool top heater. The sensor and the cartridge heater are inserted into the upper head and plugged into the controller. NOTE: The sensor must be in the head when the temperature controller is on or the cartridge heater will be uncontrolled. **WARNING: Leave the heater unplugged during set up.**

We suggest a temperature setting of approximately 37° C for tissue valves and laboratory or room temperature is suggested for the testing of mechanical valves.

Adjustment of the temperature is performed by programming the controller as follows:

1) Press the up and down arrow keys simultaneously and hold for approximately 5 seconds until the upper display reads 3 and the lower display reads "LOC."
2) Press the down arrow until the upper display reads 2, then press the mode key several times until the setpoint and actual temperature are displayed.
3) Use the arrow keys to adjust the lower display to the desired setpoint.
4) Press the up and down arrow keys simultaneously and hold for approximately 5 seconds until the upper display reads 2 and the lower display reads "LOC."
5) Press the up arrow key until the upper display reads 3 then press mode several times till setpoint and actual temperature are displayed.

NOTE: If desired, the temperature controller may be left in LOC 2 level. To do this, skip steps 4 and 5. There are four levels of lockout for the Model 985A; see page 25 of the Watlow manual for their descriptions.

NOTE: The Model 985A controller is equipped with high and low alarm circuits. If either one is exceeded, the machine will shut down if in the RUN mode.

NOTE: The alarm circuits are programmed to a deviation of -5°C (low) and +3°C (high) from the setpoint and will reset themselves when the temperature returns to this range. Therefore, it is not necessary to manually reset the temperature controller when the "start" button is pushed.

Systemic Pressure Range/Safety Shut Off

The systemic operating pressure is displayed on the front panel gauge (G2), and is monitored by a high/low pressure switch which is connected to the capacitance tank. Should a leak in the system occur or if overheating increases the pressure, the switch will remove power from the motor controller and must be manually reset. The pressure operating range is factory set to 1.5 psig (low) and 5 psig (high). These levels may be changed by opening the cabinet and adjusting the pressure switch. (For more information, see section "Pressure Switch Adjustment.")

SET UP/RUN Switch

If the operator chooses to temporarily run the machine with no systemic pressure (e.g., during set up), the safety switch can be overridden by flipping the SET UP/RUN switch on the back panel to "SET UP." This will cause the set-up light on the front panel to be illuminated, serving as a reminder that the safety switches are being bypassed. Under no circumstances should the instrument be operated unattended in this configuration.

Start/Stop

The Start/Stop switches not only perform the standard function of turning the machine on and off, but they also serve to reset the safety switches if they are activated or if power is temporarily removed from the unit. This means that if the operation of the instrument is interrupted for any reason while unattended, it will not go back on by itself. We have found this to be the best way to keep the valves from being damaged during a rapid restart. NOTE: When restarting, always begin by setting motor speed dial to 0. The start button must be depressed for 2-3 seconds to engage.

Cycle Count

Cycle counting is done on an IVO (Irion and Vosseler) Electronic Counting, Control and Monitoring Unit NE212, with a proximity sensor (also used to drive the digital speed readout).

The NE212 comes preprogrammed for its most flexible uses with the M6. The counter has a six digit display, and is programmed for two display modes, one scaled and one not scaled. The scaled mode (main counter-**XP** on legend) displays the six most significant digits and is read as millions of cycles (example: 378621 = 378.621 x 1,000,000 = 378,621,000). The unscaled display mode (batch counter-**XB** on legend) displays the six least significant digits, and would display 621.917 in the above example if the count was 378,621,917 cycles.

The NE212 is a very versatile device, and users are urged to familiarize themselves with its operation; a user's manual is included with the shipped documentation. As an example of its features, the instrument may be set to shut off when it reaches a preset number of cycles. By setting Preset 1 (**P1** on the legend) to the number of cycles you wish to test to, the counter will remove power from the motor speed controller and the temperature controller when that number of cycles is reached. When the number of cycles requested is reached, the farthest right decimal point will light up. The main counter display will clear as soon as the preset level is reached, but the totalizer (Σ on legend) will maintain the count until it is manually cleared. The batch counter will hold its display as well. It is also possible to lock the keyboard to prevent entry into the programming mode. However, this requires that you choose a locking code. If you choose to do this you must not lose or forget that locking code or the entire counter will have to be returned to the factory. Again, the user is referred to the NE212 manual for a full description of its uses. The NE212's nonvolatile memory will hold the count in excess of ten years.

Setting the Pressure and Flow Rate

The valve closure loading pressure (closing pressure) is a function of the speed, the magnitude of the bellows compression, and the setting of the center throttle valve in the valve head. The machine is capable of speeds to 2000cpm. Tissue valve flutter has been found to be an adverse operating condition so that cycle rates of 1000-2000cpm are considered to be maximal (see below). If the investigation of a particular failure mode is desired independent of longevity, higher rates and pressures may be used.

Pressure transducer taps are located at regions of equal area to give an accurate indication of pressure. The most important pressure measurement during the cycle is at valve closure when the flow is zero. The problems associated with dynamic pressure measurement are minimal at this instant so that closure loading pressure measurements are accurate. A sample differential pressure trace is shown in Figure 3. The closing spike is superimposed on a sinusoidal pressure oscillation. The minor oscillations are impulses from the closing of the other valves or bellows compression.

Fluid property variations are of little consequence at accelerated cycle rates. The Reynolds and Strouhal numbers are sufficiently supercritical that viscosity variations from 1cp to 20cp will have no effect on the flow and valve motion dynamics. Density is also not a factor since its main effect is in the determination of the pressure which is set directly.

Buffered saline is recommended for use with tissue valves. An alternate fluid is a 48% glycerol/52% saline mixture that has a viscosity about equal to that of blood at 37°C. This mixture also provides better lubrication for valve operation. In all cases, an agent to inhibit microorganisms (e.g., Kathon CG from Rohm and Haas) should be used.

There are several criteria that one must meet before proper instrument adjustment is completed. For all valve types these include:

1) Complete valve opening during each cycle (use a stroboscope).
2) Complete valve closing during each cycle (use a stroboscope).
3) Presence of a reproducible (this depends on your criteria) closing spike.
4) After 12 hours running at elevated temperatures (e.g. 37°C), no bubbles are present.

Some special considerations include:

For leaflet valves, absolutely no leaflet end flutter.

For mechanical valves, absolutely no cavitation. This can be seen as a transient flash of light as a gas bubble sweeps across the surface when viewed under a strobe light.

Lack of sensitivity to these considerations renders your testing invalid and might destroy your valves prematurely. Please be aware of these factors before you begin testing.

Tissue Valves

The following adjusting procedure is suggested for the setup of tissue valves.

Set the drive amplitude at the edge of the swashplate to 1 to 2mm, nominally 1mm for smaller valves and 2mm for larger valves. Set the throttle valve at its center position as described in the "Descriptions" section.

Insert the calibrated pressure transducers as described in the section on "Transducer Calibration." Observe the pressure trace on the oscilloscope while slowly increasing the speed. If the differential pressure exceeds its desired value, open the throttle valve a little. (See throttle valve procedure under "Descriptions.") If the pressure is not high enough, close the throttle valve a little. If the combination of speed and throttle valve settings does not produce a high enough pressure, increase the swashplate offset about 1/2mm and repeat the above procedure. If the pressure is too high, open the throttle valve, etc.

When the desired pressure and motion have been obtained, the valve test may be started.

Remember: Full opening, full closing and no leaflet flutter.

Mechanical Valves

A nominal testing cycle rate range for mechanical valves has been determined as 800-1600cpm. It is difficult to prevent cavitation at higher speeds in any accelerated rate machine.

The maximal speed for mechanical valves has been found to be limited by cavitation which occurs around the periphery of the occluder during maximal occluder motion (and therefore velocity) and at the instant of closure. Cavitation is reduced, or inhibited, by the following operating conditions: (1) minimal fluid temperature, (2) minimal flow rate, (3) minimal cycle rate, and (4) maximal system pressure. Cavitation is observed at the periphery of the occluder with a stroboscope at the instant of valve closure. It will appear as a fraction-of-a-second flash at the location of maximal occluder motion. The maximal recommended system operating pressure is 5psi. Laboratory or room temperature is suggested for testing of mechanical valves. Their material is insensitive to temperature variations from 10°C to 60°C.

Mechanical valves are more difficult to get to close for two reasons: They have a higher dynamic closing backflow, and the occluder-fluid dynamic flow conditions in both the mitral and aortic positions during closing are counter to those for a

natural or tissue valve. The test section geometry for mechanical valves is therefore different from that for tissue or original equipment valves.

Example: The dynamic closing regurgitory backflow for mechanical valves is on the order of 5-7%, or 4-5cc. The volume flow/pulse at accelerated rates is much less than at normal rates, nominally 5-6cc. The available pumping volume to produce closure is therefore severely limited. It may take more time to "tune" the system to obtain the desired combination of speed and closing pressure for mechanical valves.

The differential loading pressure for mechanical valves is set with the same procedure as described under "Tissue Valves."

Remember: Full opening, full closing and no cavitation.

Transducer Calibration

The following calibration instructions assume the use of the Dynatek XSC pressure transducer electronic control unit and appropriate pressure transducers such as the Endevco 8510B-5. Read the information that was provided with the transducers carefully. For the Endevco transducers, this would be the Endevco Instruction Manual IM8500 Rev. A, July 4, 1990. You should be familiar with all aspects of the transducers before using them.

There are two ways to calibrate the transducers. The first is performed outside the M6 with direct connection to a manometer, the second is performed inside the M6. We will be dealing with the former in this section.

After the machine has been filled and debubbled, set the system pressure to zero by opening the stopcock on top of the capacitance tank.

1) Plug the transducers into the corresponding XSC jacks under "NULL" on the front of the box.

2) Connect outputs from the XSC box to a dual-channel oscilloscope.

3) Turn XSC on.

4) Ground oscilloscope inputs and invert the channel for the B transducer.

5) Set each channel sensitivity to 200mV per division.

6) Set each channel to zero with the vertical position controls.

7) Switch the oscilloscope to DC.

8) Adjust each channel to zero with the "NULL" potentiometer on the XSC.

9) Apply 100mm Hg pressure to the system with the manometer.

10) Adjust the "GAIN" potentiometer so that each channel has a two division change (50mm Hg per division). One channel will be inverted.

11) Open the manometer to atmosphere. If the traces do not return to zero, repeat from Step 7.

12) Switch the oscilloscope to "add" and adjust the position of the channels back to zero.

13) Pressurize the system again. If the adjustments are exact there should be no movement.

NOTE: The buffered outputs of the XSC are amplified from approximately 2X at a potentiometer setting of 2 to approximately 12X at a setting of 12. When both outputs are adjusted correctly, a differential signal of zero should be obtained when 100mm Hg is imposed on both transducers simultaneously. We recommend a potentiometer setting as close to 2 as possible to result in 0mV differential signals.

The transducers are now calibrated and can be connected to the M6. Keep in mind that this process is just one example of the procedures that might be used. Actual output magnitude is at the discretion of the user.

SERVICE AND MAINTENANCE

The following section deals with the service and maintenance of the components of the M6. If you have any questions about the servicing of your machine, please call Dynatek Dalta Scientific Instruments and an engineer will help you.

Motor Drive

The motor is easily removed by first removing the four 3/8" hex head screws. The motor will drop to the table when the clamping thrust collar is loosened. A 1/2" or 1" thick pad may be placed under the motor. Lift the cylinder assembly up off the motor. Note the shims that provide for a square alignment of the motor with the motor plate. Also, note the thrust washer under the clamping ring. The bearing may be removed by removing this ring.

Brush Replacement, Inspection, and Carbon Removal

Occasionally, the motor may begin to run erratically due to carbon particle buildup from the motor brushes. In this case, it is necessary to remove the carbon particles, inspect the brushes and replace them if necessary. The procedure is given below.

Before starting this procedure, disconnect the RTD, heater, proximity sensor and DC motor cord. Place the DC motor cord and plug inside of the lower housing tube beside the motor. Depressurize the capacitance tank and remove the connecting tube from M6 and seal off the fitting.

1) Remove the two opposing sector plates from the M6.

2) Using a 3/16" hex key, loosen and remove the eight 1/4"-20 socket head cap screws holding the motor mounting plate to the lower housing tube.

3) Firmly grasp the motor mounting plate and lift upwards.

4) After clearing the lower housing tube, carefully turn the assembly on its side and place it on the bench top. Be sure to wedge blocks, foam or wood under the sides of the upper cylinder section to prevent rolling, or you can attach one of the sector plates to the motor mounting plate in a manner that will prevent rolling.

5) Using a screwdriver or 1/4" wrench, remove the two brush cover plates located just above the fan shield.

6) Follow the instructions printed on one of the brush cover plates to remove the brushes.

Checking the Brush Size:

Each brush must be a minimum of 9/16" (14mm) in length when measured on the long side. If a brush is below this limit, replace it before reassembly.

Carbon Removal:

Any loose carbon in brush/commutator area should be removed by either vacuuming or blowing with compressed air, or both, before reinstalling the brushes.

Reinstall the brushes, replace the brush cover plates and reassemble the machine.

Proximity Sensor

The proximity sensor should only have to be removed in the unlikely event that the motor or the motor bearing needs to be replaced. It is easier to remove the sensor and its mounting bracket as one unit by removing the two socket head cap screws holding the mounting bracket. To reassemble, use the socket head cap screws to lightly install the mounting bracket (with the sensor in place). Use a feeler gauge to adjust the position of the bracket so that the sensor is 0.008" from the surface of the welded tag attached to the motor shaft collar. Tighten the socket head cap screws.

Valve Head and Throttle Valve

The top plate and valve blocks are removed as described under "Valve Removal." The center throttle valve cylinder is removed by first backing off its jack screws and then lifting it with a rotary oscillating motion.

Pumping Unit

First, remove the eight socket head cap screws around the outside of the aluminum clamping ring that clamp the bottom plate to the top cylinder sectors. Leave two opposite screws in until the remaining six are out. Then unscrew these two alternately about one turn at a time (or both at the same time). The bellows are pre-compression loaded 0.1". They last longer in compression than in tension,

and a positive sealing pressure is maintained on the o-rings. This bottom plate and ring should be pulled down evenly when reassembling. (Do not remove the inner ring of eight stainless steel cap screws. Removal of the ring from the plate is never necessary except in case of breakage.)

Loosen the three tilt coupling clamp screws and lift off the pumping unit. It may be necessary to pry up on the coupling between it and the shaft collar with a large screwdriver to get it started. It is necessary to lift from under the bottom of the tilt coupling since it will cock and bind if the unit is lifted by the swashplate. The coupling is keyed to the motor shaft.

Aligning the coupling, key and motor shaft is a little tedious, but not difficult, when reassembling.

WARNING: The coupling clamp screws should always be tightened securely before operating the machine!

NOTE: Three of the cylinder sectors have been left attached to the motor plate.

Inside the Control Console

Although not usual, it may be necessary to perform some work on the inside of the M6 control box. For instance, you may need to replace fuses for individual components such as the counter, speed indicator, etc., or to adjust the pressure switch settings.

Opening Top Cover

First turn the main power switch OFF and unplug the control box from its power source. Remove the button screws from the sides of the cabinet, and lift the cover. The unit is now ready for service. The control box may be run for short periods with the cover open, but the cover should be closed for proper cooling during long operations.

Fuse Replacement

In addition to the main power fuse (15 amp) on the rear of the controller, there are seven others located in three areas within the control box. Two inline fuse blocks are located on the motor speed controller board. This board is positioned on the left side of the cabinet just below the digital speed readout. The right fuse is a line fuse (ABC12), and the left fuse is the armature (MDA2). Four fuses are located on the rear wall of the cabinet and are listed below from top to bottom:

Heater	3 amp
Counter	1/4 amp

Relay	1/4 amp
Fan/Set Up Lamp	1/4 amp

The final fuse (1/4 amp) is located on the bottom panel just below the temperature controller.

Pressure Switch Adjustment

Remove the cover plate from the pressure switch located behind the temperature controller. Remove all tools and the cover plate from the M6 and reconnect the power to supply source, turn the main power ON, and put the SET UP/RUN switch in the RUN position. Connect the pressure tube and the manometer and pump up to halfway between desired high/low setpoints. Make sure the temperature is within the deviation range of the setpoint. Next, press the green start button (D) and observe the temperature controller display. If the display does not stay lit, you may already be above or below the present setpoints. In this case turn the top dial counterclockwise (ccw) and the bottom dial clockwise (cw). Again press the green start button (D); controller display should stay lit. If not, repeat the above procedure.

Once the motor is running at a pressure that is halfway between the desired high/low setpoints, slowly raise the pressure until the switch is tripped and the display goes dark. If this pressure is too high, turn the bottom dial (ccw) and repeat until the desired high point is set. Then with a pressure slightly less than the high set point, slowly reduce the pressure until the switch is tripped and the display goes dark. Adjust the top dial (cw) to increase or (ccw) to decrease and repeat the above procedure until the desired low set point is set.

Replace the pressure switch cover and tighten the screws.

Turn the M6 off and disconnect it from the power source, replace the cover and mounting screws.

Reassembly

Set the motor on end with the shims in place and drop the cylinder, motor plate, and thrust bearing assembly over the motor shaft. It may be necessary to put a block under the motor to get the shaft far enough through the thrust bearing bore. Rotate the cylinder assembly until the motor face holes line up and insert the screws a few turns. Do not put any tightening pressure on these screws yet. Install the thrust washer and thrust collar and tightly tighten it. Carefully turn this sub-assembly upside down. Loosen the thrust collar, hold it against the washer and bearing and tighten it tightly. This procedure allows the thrust to be taken by the thrust bearing and the motor plate, rather than by the motor

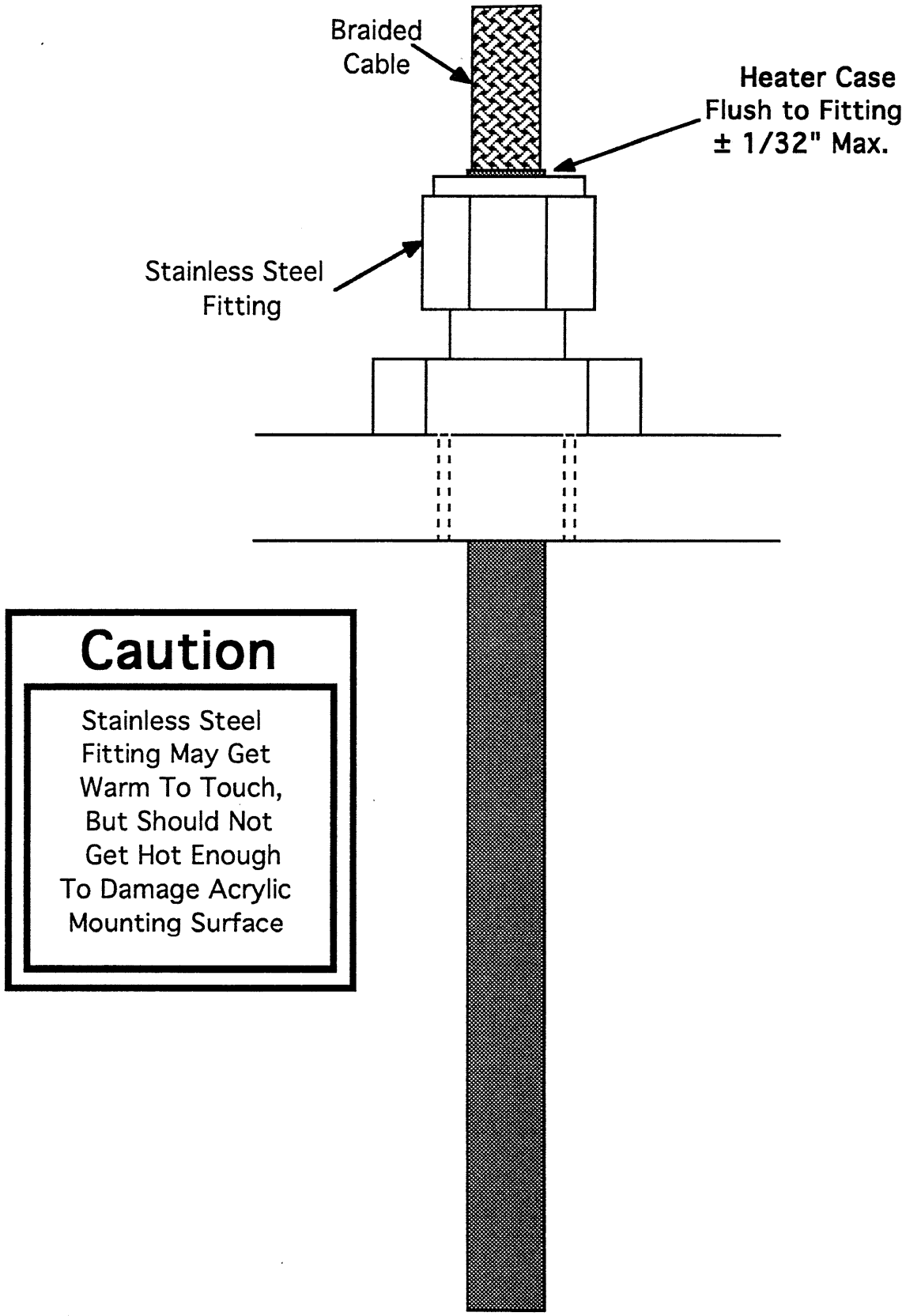
bearings, and provides a more positive motor shaft positioning. Tighten the four socket head screws, lightly the first time, then tightly in a crosswise pattern.

CLEANING AND STERILIZATION

Clean all parts of the machine with Alconox or a similar laboratory cleaner and rinse thoroughly. Machine sterility should be maintained throughout testing by incorporating an appropriate anti-microbial such as Kathon CG (Rohm and Hass). Sterilization after cleansing should be accomplished with a non-oxidizing agent such as isopropyl alcohol or a glutaraldehyde containing rinse. Under no circumstances should bleach be used since this and other oxidizing sterilizers will compromise bellows life.

WARNING: DO NOT USE BLEACH.

APPENDICES



Proper Heater Installation

Starting Counter From A Number Other Than Zero

The example below is to load 125,000,000 cycles and set preset to 150,000,000:

Press **PR** then **F** then the arrow (➜) until the legend light below **SC** lights up. Next, press **C** to clear current setting. Enter 125000. Press **PR** to exit the programming mode.

Next, press **PR** then **F** then the arrow (➜) until the legend light under **P1** lights up. Press **C** to clear current setting. Then enter 150000. Press **PR** again to exit the programming mode.

The totalizer will continue to count from whatever number it was on unless you reset this count also. To do this, press **PR** then **F** then the arrow (➜) until the legend light under **Σ** lights up. Press **C** to clear the current setting. Then press **PR** again to exit the programming mode.

Doing this will start your counter counting at 125,000,000 cycles and will stop the count when it has reached 150,000,000 cycles, so that the actual number of cycles the counter is set to count will be 25,000,000.

Troubleshooting

PROBLEM	CHECK THIS
Machine is not running	Has the preset number of cycles been reached? Check that the temperature is within the desired range -5°C (low) and +3°C (high) from 37° C. Check that the pressure is within the desired range.

To Change or View Modes On IVO NE212 Counter

Legend lights:

XP - Main counter, scaled.

P1 - Preset level One. Sets the number of cycles you want the machine to run.

SC - Start count. You can program the counter to start the count at a number other than zero. For instance, if you have run the valves for twenty million cycles and stopped the machine to check them, and you want to start the count from twenty million, it will show on the totalizer (Σ) and on the batch counter but not on the main counter.

Σ - Totalizer (sum). Keeps the total number of cycles. Six most significant digits.

XB - Batch counter, unscaled.

To Change Preset Level:

The example below sets the preset level to 125,000,000:

Press **PR** then **F** then **arrow (→)** until the light under **P1** goes on. Press **C** to clear the current preset level. Now enter the desired preset level. For 125,000,000 enter 125000. When you have entered the new level, press **PR** to leave the programming mode. Resetting the preset level will reset both the main and batch counters.

To view Preset level:

Press the **arrow (→)** until the small legend light below **P1** lights up.

Step Down Power Supply

The optional step down power supply is intended for use where 110VAC 50-60Hz is unavailable. This unit will convert 220VAC 50-60Hz to 110VAC 50-60Hz.

Input Power:

The detachable cord supplied with the step down power supply is fitted with a connector on one end which attaches to the rear of the unit. The other end needs to be fitted with the appropriate plug (not supplied) for your application.

Wire Color Code:

Brown	=	Line or Hot
Blue	=	Neutral
Green/Yellow	=	Earth Ground

Both line and neutral are fused, each with an ABC 6 fuse.

Output Power:

Two receptacles are located on the rear panel, which can be used to power devices requiring 110VAC 50-60Hz and have a current rating less than 5 amps total. Outputs are also fused with an ABC 6 fuse.

Operation:

After attaching the plug (not supplied) to the power cord and connecting it to the step down power supply, plug into a 220VAC 50-60Hz outlet. Flip the switch to the "on" position; the indicator lamp on front panel should glow. If not, check the plug connections and the input and output fuses. Turn the unit off and connect 110VAC 50-60Hz devices and return the switch to the "on" position.

For any questions concerning this machine, or if any problems arise with its operation, please feel free to call:

DYNATEK DALTA® SCIENTIFIC INSTRUMENTS
FOURTH AND MAIN STREETS
POST OFFICE BOX 254
GALENA, MO 65656
(417) 357-6155
FAX (417) 357-6327

INDEX

Dynatek Dalta®

Scientific Instruments

Dynatek Dalta®
division of
Dynatek Laboratories Inc.
Corporate Offices
4th and Main
P.O. Box 254
Galena, MO 65656-0254
Tel: 417-357-6155
Fax: 417-357-6327

September 20, 1993

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A l'attention de M. Ponchon

Shipment for:

SICN
BP 1-38113
Veurey-Voroize
FRANCE

Re: N°930170/03

BOX NUMBER	QUANTITY	ITEM
1	1	Model M6 Valve durability testing device Serial# 9320-01A
2	1 1	DC5000 controller (serial #9320-01C) Line cord
3	1 1 1 1 1 1 set (6)	Upper head Capitance tank Tool kit Throttle valve Manual Test sections (size 25)

SHIPMENT COMPLETE

FED. I.D. NO. 91-0837469 SCAC-AIRB

1 SENDER'S AIRBORNE EXPRESS ACCT. NO.: 6443850

ORIGIN AIRBILL NO.: 8074287550

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